

in any one year." The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the companion direct final rule have been approved by OMB in accordance with the PRA under the regulations governing labeling of medical devices (21 CFR part 801, OMB control number 0910–0485).

VIII. What Are the Federalism Impacts of This Proposed Rule?

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments on this recommendation. Submit electronic comments to <http://www.regulations.gov>. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the name of the device and the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management

System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

List of Subjects in 21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 801 be amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

2. Section 801.420 is amended by revising the second and third sentences of and adding a new fourth sentence to paragraph (c)(4) introductory text and by removing paragraph (d) to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

* * * * *

(c) * * *

(4) * * * The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22–2003 (Revision of ANSI S3.22–1996) (Includes April 2007 Erratum). The Director of the Office of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). * * *

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Dated: May 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–11909 Filed 5–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

[SATS No. WY–036–FOR; Docket ID OSM–2008–0008]

Wyoming Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; opening of public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of a proposed amendment to the Wyoming Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter, the Wyoming Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Wyoming intends to revise its Plan by submitting a revision to correct an inadvertent error in the statute amendment passed in the 2007 Legislative Session.

DATES: Comments on the proposed rule must be received by 4 p.m., m.d.t., July 2, 2008 to ensure our consideration. If requested, we will hold a public hearing on the amendment on June 27, 2008. We will accept requests to speak until 4 p.m., m.d.t., June 17, 2008.

ADDRESSES: You may submit comments by either of the two following methods:

- **Federal e-Rulemaking Portal:** <http://www.regulations.gov>. The notice is listed under the agency name "Office of Surface Mining Reclamation and Enforcement" and has been assigned Docket ID: OSM–2008–0008.
- **Mail/Hand Delivery:** Jeffrey Fleischman, Director, Casper Field Office; Office of Surface Mining Reclamation and Enforcement; 150 East "B" Street, Room 1018, Casper, Wyoming 82601. Please include the Docket ID (OSM–2008–0008) with your comments.

If you would like to submit comments through the Federal e-Rulemaking Portal, go to <http://www.regulations.gov> and do the following. Click on the "Advanced Docket Search" button on the right side of the screen. Type in the Docket ID OSM–2008–0008 and click the "Submit" button at the bottom of the page. The next screen will display the Docket Search Results for the rulemaking. If you click on OSM–2008–0008, you can view the proposed rule and submit a comment. You can also

view supporting material and any comments submitted by others.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than the two listed above will be included in the docket for this rulemaking and considered.

For additional information on the rulemaking process and the public availability of comments, see “III. Public Comment Procedures” in the **SUPPLEMENTARY INFORMATION** section of this document.

You may receive one free copy of this amendment by contacting OSM’s Casper Field Office. You may access this amendment’s docket, review copies of the Wyoming Plan and this amendment, find a listing of any scheduled public hearings, and review all written comments received in response to this document during normal business hours, Monday through Friday, excluding holidays, at the following addresses:

Federal e-Rulemaking Portal: <http://www.regulations.gov>. The notice has been assigned Docket ID: OSM–2008–0008.

Jeffrey Fleischman, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, 150 East “B” Street, Room 1018, Casper, Wyoming 82601, (307) 261–6550, jfleischman@osmre.gov.

Rick Chancellor, AML Administrator, Department of Environmental Quality, Herschler Building, 122 West 25th Street, Cheyenne, Wyoming 82002, 307–777–7062.

FOR FURTHER INFORMATION CONTACT:

Jeffrey Fleischman, Casper Field Office Director, Telephone: (307) 261–6550, Internet address: jfleischman@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Wyoming Plan
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Wyoming Plan

The AMLR Program was established by Title IV of the Act (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the

Secretary of the Interior for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines.

On February 14, 1983, the Secretary of the Interior approved Wyoming’s AMLR Plan. You can find general background information on the Wyoming Plan, including the Secretary’s findings and the disposition of comments, in the February 14, 1983, **Federal Register** (48 FR 6536). OSM announced in the May 25, 1984, **Federal Register** (49 FR 22139), the Director’s decision accepting certification by Wyoming that it had addressed all known coal-related impacts in the State that were eligible for funding under the Wyoming Plan. Wyoming could then proceed in reclaiming low priority non-coal projects. The Director accepted Wyoming’s proposal that it would seek immediate funding for reclamation of any additional coal-related problems that occur during the life of the Wyoming Plan. You can find later actions concerning Wyoming’s Plan and plan amendments at 30 CFR 950.35.

II. Description of the Proposed Amendment

By letter dated March 21, 2008, Wyoming submitted a proposed amendment to the Wyoming Reclamation Plan. Wyoming submitted the amendment in response to a letter sent to the State dated January 18, 2008, from the Regional Director, Western Region of OSM. Pursuant to 30 CFR 884.11, OSM directed Wyoming to resolve a conflict in Wyoming accounts established to receive funds from the Federal Government pursuant to the SMCRA program.

Specifically OSM stated it appears that Wyoming’s new statute, WS–35–11–1210 conflicts with existing WS–35–11–1203. WS–35–11–1210 was passed in 2007 and established an account to receive funding under new section 411(h) of SMCRA. These funds are not required to be spent on reclamation projects.

Wyoming’s proposed amendment clarifies that the account established by WS–35–11–1210 is for the purpose of receiving funds from the Federal Government pursuant to SMCRA Section 411(h) and that these funds are separate and in addition to funds distributed to the account established by WS–35–11–1203. The WS–35–11–1203 account remains to receive funds to carry out the Reclamation Plan including coal reclamation.

The full text of the plan amendment is available for you to read at the locations listed above under **ADDRESSES**.

III. Public Comment Procedures

Under the provisions of 30 CFR 884.15(a), OSM requests your comments on whether the amendment satisfies the applicable State reclamation plan approval criteria of 30 CFR 884.14. If we approve the amendment, it will become part of the Wyoming Plan.

Electronic or Written Comments: If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed above (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments: Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available in the electronic docket for this rulemaking at <http://www.regulations.gov>. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing: If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., m.d.t., on June 17, 2008. If you are disabled and need reasonable accommodation to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold the hearing. If there is only limited interest in participating in a public hearing, a public meeting rather than a hearing may be held, and a summary of the meeting will be included in the docket for this rulemaking.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy

of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

IV. Procedural Determinations

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects on federally recognized Indian Tribes and have determined that the proposed amendment does not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The proposal does not affect Indian Tribes in any way.

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis of the amendment submitted by Wyoming.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of Tribe or State AMLR plans and revisions since each such plan is drafted and promulgated by a specific Tribe or State, not by OSM. Decisions on proposed Tribe or State AMLR plans and revisions submitted by a Tribe or State are based on a determination of whether the submittal meets the requirements of Title IV of SMCRA (30 U.S.C. 1231–1243) and the applicable Federal regulations at 30 CFR parts 884 and 888.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

No environmental impact statement is required for this rule since agency decisions on proposed Tribe or State AMLR plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior at 516 DM 13.5.B(29).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This determination is based upon the nature of the amendment submitted by Wyoming as discussed above.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), of the Small Business Regulatory Enforcement Fairness Act. Based on the nature of the amendment submitted by Wyoming, we have determined that the rule:

- a. Does not have an annual effect on the economy of \$100 million.
- b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or Tribal governments or the private sector of \$100 million or more in any given year. This determination is based on the nature of the amendment submitted by Wyoming.

List of Subjects in 30 CFR Part 950

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 13, 2008.

James Fulton,

Acting Regional Director, Western Region.

[FR Doc. E8–12199 Filed 5–30–08; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0392]

RIN 1625–AA08

Special Local Regulations for Marine Events; Patapsco River, Inner Harbor, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations during the “Pride of Baltimore Recycled Regatta”, a marine event to be held August 2, 2008 on the waters of the Patapsco River, Inner Harbor, Baltimore, MD. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to temporarily restrict vessel traffic in a portion of the Baltimore Inner Harbor during the event.

DATES: Comments and related material must reach the Coast Guard on or before July 2, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0392 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.